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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,864	07/13/2001	Robert W. Blakesley	0942.5050002/RWE/AGL	9639
26111	7590	01/02/2004		
		STERNE, KESSLER, GOLDSTEIN & FOX PLLC		EXAMINER
		1100 NEW YORK AVENUE, N.W.		MOHAMED, ABDEL A
		WASHINGTON, DC 20005	ART UNIT	PAPER NUMBER
				1653

DATE MAILED: 01/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/903,864	BLAKESLEY ET AL.	
Examiner	Art Unit		
Abdel A. Mohamed	1653		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 04 November 2003.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-37 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-37 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

13)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a)  The translation of the foreign language provisional application has been received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_ .  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 5)  Notice of Informal Patent Application (PTO-152)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6,7,9,11 . 6)  Other: \_\_\_\_\_ .

## **DETAILED ACTION**

### **ACKNOWLEDGMENT OF PRELIMINARY AMENDMENT, IDS, RESTRICTION**

### **REQUIREMENT AND STATUS OF THE CLAIMS**

1. The preliminary amendment filed 10/31/01, the information disclosure statement (IDS) and Form PTO-1449 filed 11/8/01, 11/14/02, 3/18/03 and 10/14/03, and the response to the restriction requirement filed 10/14/03 are acknowledged, entered and considered. However, some of the references provided by Applicant were not considered. Reference AS is a PCT search report, which does not contain a place of publication, and reference AT2 is a copending application No. 09/478,456, which has not been published or patented, therefore, reference to it cannot be printed in case the present application is allowed. Claims 1-37 are now pending in the application.

### **ELECTION WITH TRAVERSE**

2. Applicant's election with traverse of Group I (claims 1-20) in Paper No. 11 is acknowledged. The traversal is on the ground(s) that there is a close relationship between the subject matter of the Group I and II claims, there would be no serious burden on the Examiner to examine both sets of claims at this time. Groups I and II are classified in the same class, and a search of one group of claims is likely to encompass subject matter pertinent to the patentability of the other group. As such, there is a close relationship between the subject matter of these three sets of claims. It is believed that there would be no serious burden on the Examiner to examine all of claims 1-37 together at this time. The Examiner agrees Applicant's characterization with respect to

Groups I and II that there is a close relationship between the subject matter of these three sets of claims because the search of one group of claims encompass subject matter pertinent to the patentability of the other group as asserted by Applicant. Thus, the claims will be rejoined and examined together. Hence, the Office action is directed to the merits of claims 1-37.

#### **ABSTRACT OF THE DISCLOSURE: LANGUAGE**

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," and in the instant case including "e.g.," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

### **OBJECTIONS TO TRADEMARKS AND THEIR USE**

4. The use of the trademarks "Bug Buster™", "Benzonase®", BRIJ® 35", "ELUGENT™", GENAPOL® C-100", "GENAPOL® 080", "GENAPOL® X-100", "PLURONIC® F-127", "TRITON® X-100", "TRITON® X-114", "TWEEN® 20" and "TWEEN® 80" have been noted in this application. Some of the trademarks have not been capitalized, they should be capitalized wherever they appear and be accompanied by the generic terminology. Although, the use of trademarks are permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in a manner which might adversely affect its validity as trademarks.

Further, the specification, which specifies the generic terminology should include, published product information sufficient to show that the generic terminology or the generic description are inherent in the article referred by the trademarks. These description requirements are made because the nature and composition of articles denoted by trademarks can change and affect the adequacy of the disclosure.

### **CLAIMS REJECTION-35 U.S.C. § 112<sup>2nd</sup> PARAGRAPH**

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10 are incomplete in failing to recite a process step(s) wherein the protein or peptide molecules released from cellular sources. There is no showing how the proteins or peptides are released from the cellular sources. Incorporation of the subject matter of claim 11 into claim 1 with the explanation of how the "matrix" is modified to permit the limitation of claim 11 is suggested.

Claims 1, 20 and 21 are indefinite in the recitation "substantially" because the term "substantially" is a relative term, which does not identify the exact value, degree, amount, or extent of the claimed subject matter. Thus, deletion of the term "substantially" would obviate this rejection.

Claim 7 recites the limitation "said release" in line 1. There is insufficient antecedent basis for this limitation in claim 1 or claim 7.

In claim 9, the term "comprises" is incomplete because additional subject matter not specified in claim 7 has been added rendering claim 9 lacking proper antecedent basis. Amendment of the claim to read "further comprising" is suggested.

Claim 12 recites the limitation "said filter" in line 2. There is insufficient antecedent basis for this limitation in claim 1 or claim 12.

Claims 13 and 14 are indefinite in misspelling "chaetotropic". It is believed to be typographical error. Appropriate correction is required.

Claim 15 is indefinite in failing to recite how the protein or peptide molecules are collected. Is it by chromatographic procedure or by filtration or by dialysis or by centrifugation?. Appropriate clarification is required.

Claim 20 is indefinite in the recitation "optionally" because if an ingredient, a step, or other structural element is truly optional i.e., its presence is not necessary for attainment of the result that is an object of the invention, then recitation thereof does not belong to the claim.

Claims 21, 34 and 35 are indefinite in the recitation "...compositions capable of being used for detecting or quantifying....". Amendment of the claims to recite "...compositions which detect or quantify....." is suggested.

Claim 23 recites the limitation "said tube" in line 2. There is insufficient antecedent basis for this limitation in claim 21 or claim 23.

#### **CLAIM REJECTION-35 U.S.C. § 102(b)**

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 7-8, 11-16 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kinsella et al. (U.S. Patent No. 4,427,580).

Kinsella et al. is directed like the instantly claimed invention of claims 1-2, 7-8, 11-16 and 18-20 to a method for extracting and isolating proteins or peptide molecules from cells (e.g., bacterial cells, animal cells, fungal cells, viruses, yeast cells or plant cells) via disruption and use of chaotropic agent and recovering the peptide or protein by conventional filtration methods ( See e.g., cols. 2-5, Figure 1 and the claims) as directed to claims 1-2, 7-8 and 17-18.

With respect to claim 19, claim 19 is presented in product-by-process format, and as such, it is the novelty and patentability of the instantly claimed product that need be established and not the recited process steps, *In re Brown*, 173 USPQ 685 (CCPA 1972); *In re Wertheim*, 191 USPQ (CCPA 1976). Further, the prior art described the product as old, *In re Best*, 195 USPQ 430, 433 (CCPA 1977); (See MPEP 706.03 [e]). Hence, the burden of proving that the process limitation makes a different product is shifted to Applicants. *In re Fitzgerald*, 205 USPQ 594.

In regard to claim 20, the cited reference above does not disclose the intended use of the composition for isolating a protein or peptide molecule, although, the reference discloses the process of extracting and isolating proteins or peptide molecules; nevertheless, a statement of usefulness or contemplated use of a claimed compound or composition in a claim is usually given little weight in distinguishing over the prior art. *In re Maeder et al.* (CCPA 1964) 337 F2d 875, 143 USPQ 248; *In re Riden et al.* (CCPA 1963) 318 F2d 761, 138 USPQ 112; *In re Sinex* (CCPA 1962) 309 F2d 488, 135 USPQ 302. Further, it is well established that the intended use of a compound (e.g., a polypeptide or a protein or a glycoprotein) does not impart patentability to the compound. *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990) (The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims

to the known composition); *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claims patentable); *In re Zierden*, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969). Thus, the prior art discloses the invention substantially as claimed, and as such, anticipates claims 1-2, 7-8, 11-16 and 18-20 as drafted.

7. Claims 1-2, 7-9, 11-16 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshimura et al. (U.S. Patent No. 3,923,600).

Yoshimura et al. is directed like the instantly claimed invention of claims 1-2, 7-9, 11-16 and 18-20 to a method for extracting and isolating proteins or peptide molecules or enzymes from cells (e.g., bacterial cells, animal cells, fungal cells, viruses, yeast cells or plant cells) via disruption and use of chaotropic agent and recovering the peptide or protein by conventional filtration methods (See e.g., abstract and cols. 1-3) as directed to claims 1-2, 7-9 and 17-18.

With respect to claim 19, claim 19 is presented in product-by-process format, and as such, it is the novelty and patentability of the instantly claimed product that need be established and not the recited process steps, *In re Brown*, 173 USPQ 685 (CCPA 1972); *In re Wertheim*, 191 USPQ (CCPA 1976). Further, the prior art described the product as old, *In re Best*, 195 USPQ 430, 433 (CCPA 1977); (See MPEP 706.03 [e]). Hence, the burden of proving that the process limitation makes a different product is shifted to Applicants. *In re Fitzgerald*, 205 USPQ 594.

In regard to claim 20, the cited reference above does not disclose the intended use of the composition for isolating a protein or peptide molecule, although, the reference discloses the process of extracting and isolating proteins or peptide molecules; nevertheless, a statement of usefulness or contemplated use of a claimed

compound or composition in a claim is usually given little weight in distinguishing over the prior art. *In re Maeder et al.* (CCPA 1964) 337 F2d 875, 143 USPQ 248; *In re Riden et al.* (CCPA 1963) 318 F2d 761, 138 USPQ 112; *In re Sinex* (CCPA 1962) 309 F2d 488, 135 USPQ 302. Further, it is well established that the intended use of a compound (e.g., a polypeptide or a protein or a glycoprotein) does not impart patentability to the compound. *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990) (The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition); *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claims patentable); *In re Zierden*, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969). Thus, the prior art discloses the invention substantially as claimed, and as such, anticipates claims 1-2, 7-9, 11-16 and 18-20 as drafted.

#### **CLAIMS REJECTION-35 U.S.C. § 103(a)**

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kinsella et al. (U.S. Patent No. 4,427,580) or Yoshimura et al. (U.S. Patent No. 3,923,600) taken with Yoshioka et al. (U.S. Patent No. 4,347,316) or Henco et al. (U.S. Patent No. 5,652,141) or Shah et al. (U.S. Patent No. 4,303,530).

The prior art of Kinsella et al. or Yoshimura et al. as discussed above, each discloses like the instantly claimed invention methods of extracting and isolating proteins or peptide molecules from cells such as bacterial cells, animal cells, fungal cells, viruses, yeast cells or plant cells via lysis and/or disruption and one or more additional isolation procedures, such as filtration and/or chromatographic procedures. Kinsella et al. or Yoshimura et al. differ from claims 1-37 in not teaching the use of a pore-containing matrix with the pore sizes claimed and an apparatus containing a housing, pore-containing matrix and chromatographic resin and a kit formulation thereof. However, the patent of Yoshioka et al. discloses a process for isomerizing a glucose containing solution to convert a part of glucose to fructose by a method of isomerization in which the separation of fructose from the isomerized glucose solution may be carried out by conventional procedure. That is, the isomerized glucose solution is brought into contact with a matrix such zeolite having pores at least 5 angstroms in

average diameter, whereby fructose and glucose contained in the isomerized glucose solution is adsorbed in the zeolite; and then, the adsorbed fructose is eluted from the zeolite particles. Thus, clearly showing the use of a matrix such as zeolite having pores at least 5 angstroms in average diameter (See e.g. col. 8). Further, Shah et al. teach the use of a filter for removing microaggregates from the blood and blood components having a pore size and/or diameter of about 400 to microns (See e.g., cols 1-3) as directed to claims 4-6 and 28. Furthermore, the reference of Henco et al. on col. 2 and Figure 1 discloses the use of a device having matrix size from 1 to 50  $\mu\text{m}$  in which the cell immobilized with matrix are lysed using detergent and eluted by adjusting to high ionic strength subsequent to various washing operations. Thus, the reference clearly teaches the use of an apparatus containing a housing, a pore-containing matrix and a chromatographic resin as directed to claims 21-32.

Therefore, given the teachings of the primary references of Kinsella et al. and Yoshimura et al., one of ordinary skill in the art would have been motivated to adapt the above scheme of using of a pore-containing matrix and an apparatus containing a housing, pore-containing matrix and a chromatographic resin. Further, such features are known or suggested in the art, as seen in the secondary references, and including such features into methods and compositions for protein and peptide extraction and isolation via lysis and/or disruption methods of the primary references would have been obvious to one of ordinary skill in the art to obtain the known and recognized functions and advantages thereof.

With respect to the kit, the secondary reference of Henco et al. discloses an apparatus containing a housing, a pore-containing matrix and a chromatographic resin; however, from the cited references, it is conventional and within the ordinary skill in the art based upon the teachings of the combined references to have such

kits/compositions as set forth in claims 33-37 since the combined references teach using these compositions together in the same formulation that would have been found in the claimed composition and/or kits to formulate compositions into a kit format because the claimed kit is tailored for use in claimed apparatus kit formulation comprising the composition claimed. Hence, it would have been obvious to package the composition required for the method into kit format of the well-known commercial expediency of doing so.

Therefore, the combined teachings of the prior art makes obvious the claimed invention because at the time the invention was made based on the combined teachings of the prior art and for the reasons given above; one of ordinary skill in the art would have easily adapt the already known methods and apparatus and kit formulation thereof for use in extracting and isolating proteins or peptide molecules from cells such as bacterial cells, fungal cells, viruses, yeast cells, or plant cells via lysis and/or disruption and one or more additional isolation procedures such as filtration and/or chromatographic procedures; absent of sufficient objective factual evidence or unexpected results to the contrary.

#### **CONCLUSION AND FUTURE CORRESPONDENCE**

9. No claim is allowed.

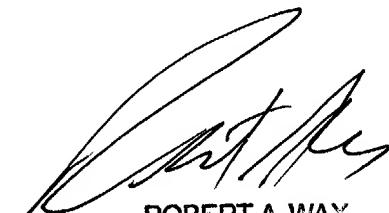
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*AAM* Mohamed/AAM

December 29, 2003



ROBERT A. WAX  
PRIMARY EXAMINER